K071756

Pointe Conception Medical, Inc
121 E. Mason Street
Santa Barbara, California 93101

AUG 15 2007

June 20, 2007

Modified--510(k) Summary
As required by section 807.92(c)

Endohub-1.0 Endoscopic Video Camera with Video Capture

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Pointe Conception Medical, Incorporated is hereby submitting the 510(k) summary of the Safety and Effectiveness for the Endohub-1.0 Endoscopic Video Camera System 510(k) number K071756

1. Submitter [510(k) owner]

Pointe Conception Medical, Incorporated.
121 E. Mason Street
Santa Barbara, California 93101

2. Company Contact

William C. Haack
VP, Engineering
805-884-0403 Ext. 103
805-884-00260 [FAX]
wchaack@pc-medical.com

3. Submitted Device Information

Common Name:	Endoscopic Video Camera System
Trade Name:	Endohub-1.0 Endoscopic Video Camera System with Video Capture
Classification Name:	Endoscope And/Or Accessories

4. Classification Information

Classification:	Class II
Classification Regulation:	876.1500
Classification Product Code:	KOG
FDA Subsequent Product Code:	GCJ

5. Legally Marketed Predicate Devices

Information on devices to which substantial equivalence is claimed			
510(k) Number	**Device Description**	**Manufacturer**	**Substantial Equivalence Comments**
K031098	Autoclavable 3-CCD Digital Camera System	Linvatec Corporation	

6. Submitted Device Description

The Endohub-1.0 Endoscopic Video Camera System is a video camera system which consists of a Camera Control Unit [CCU] and Camera Head. The Endohub-1.0 Camera System is used in conjunction with an endoscope to allow for visualization during minimally invasive surgical procedures. Sterilization of the camera head may be required prior to use. The camera head may be steam sterilized. The camera head may utilize 1CCD or 3CCD image sensors, and employ either fixed or variable focal length optics.
The Endohub-1.0 Camera System incorporates an image capture system which allows for the capture of streaming video or still video images.

7. Intended Use

The Endohub-1.0 Endoscopic Video Camera System is intended to be used as an endoscopic video camera in a variety of endoscopic surgical procedures, including but not limited to; orthopedic, laparoscopic, urologic, sinuscopic and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic surgery.
The Endohub-1.0 system allows for presentation of the endoscopic or microscopic images onto video monitors.

8. Substantial Equivalence

The Endohub-1.0 Endoscopic Video Camera System is substantially equivalent to the predicate video camera system [K031098-Linvatec Corporation-Autoclavable 3-CCD Digital Camera System] in regard to indications for use, basic design, energy delivered, biocompatibility, performance, standards used, materials, safety and effectiveness and labeling.

There are no significant differences in the new device which raise issues of safety or effectiveness. Accordingly, Pointe Conception Medical, Incorporated believes that the Endohub-1.0 Endoscopic Video Camera System is substantially equivalent to the predicate devices currently on the market.

9. Standards Compliance

The Endohub-1.0 Endoscopic Video Camera System has been tested and found to comply with the relevant international Medical Device Standards for Safety.

IEC 60601-1	Medical Electrical Equipment, General Standards
IEC 60601-2-18	Medical Electrical Equipment, Particular Requirements for Endoscopic Equipment
IEC 60601-1-2	Medical Electrical Equipment, Requirements for Electromagnetic Compatibility

PC Medical

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REF: Endohub-1.0 Endoscopic Video System 510(k) summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

Pointe Conception Medical, Inc.
% Mr. William C. Haack
VP Engineering
121 E. Mason Street
Santa Barbara, California 93101

Re: K071756
Trade/Device Name: Endohub-1.0 Endoscopic Video Camera with Video Capture
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 26, 2007
Received: June 28, 2007

Dear Mr. Haack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071756

Indications for Use

510(k) Number (if known):

Device Name: Endohub-1.0 Endoscopic Video Camera with Video Capture

Indications For Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071756